GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2194
ANSWERED ON:06.05.2016
Shortage of Staff at DCGI
Sigriwal Shri Janardan Singh

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether there is shortage of staff at Drug Controller General of India (DCGI) for review of report and application for clinical trials of drugs;

(b) if so, the details thereof along with the measures taken by the Government to fill the vacancies;

(c) whether the Government proposes to enhance e-Governance to file, track and receive approval online for clinical trials and if so, the details thereof; and

(d) the steps taken by the Government to harmonise the regulatory mechanism with international guidelines for clinical trials in India to boost pharma industry?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE
(SHRI JAGAT PRAKASH NADDA)
(a) & (b): In order to keep pace with the increasing responsibility, the manpower of the Central Drugs Standard Control Organization (CDSCO) has been increased from 111 (as in April, 2008) to 474. Further, the Government has approved a scheme for strengthening the drug regulatory system in the country which also includes provision for creation of more posts for CDSCO.

(c): CDSCO, as part of the e-Governance organisation wide project, has launched an online portal 'SUGAM' for filing, tracking and processing various services provided by CDSCO. Phase I of the Clinical Trial module has been operationalized.

(d): Clinical trials of new drugs are regulated under the Drug and Cosmetics Rules, 1945 as amended from time to time. The best international practices have been accommodated in these rules to ensure that there is no compromise in the conduct of clinical trials and the safety and welfare of the patients is ensured.